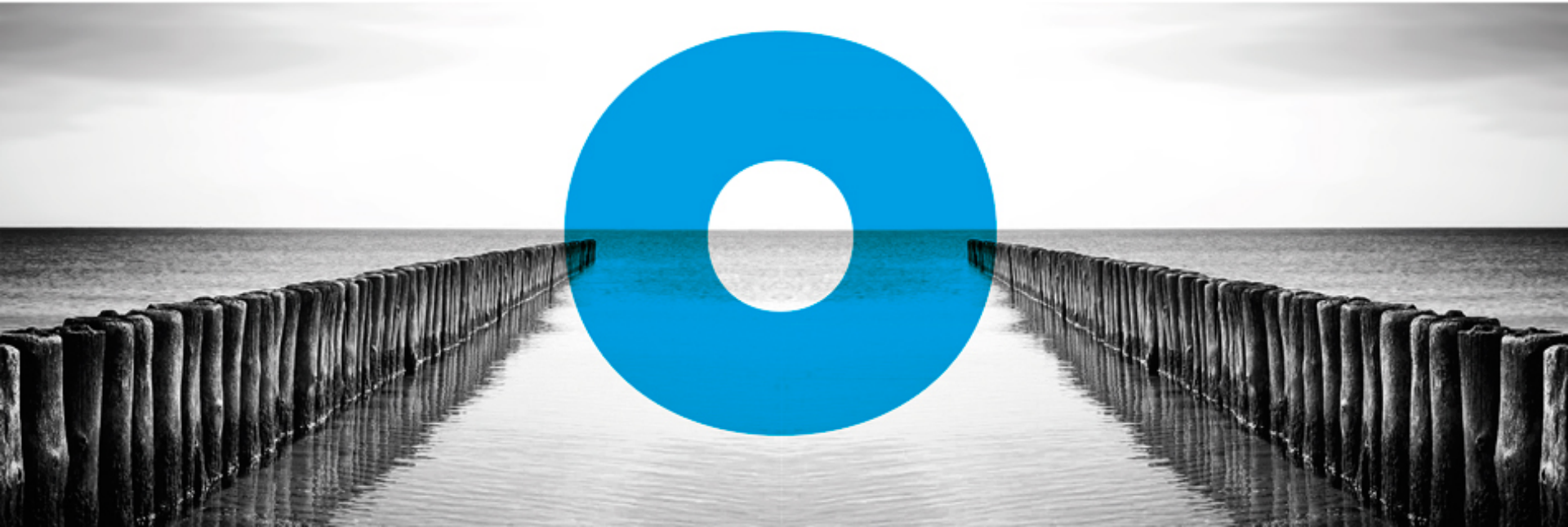




OUTSOURCING AND OFFSHORING

Let me introduce myself

My name:

Mark Bynens

My hometown:

Zonhoven (Limburg)



Professionally

Senior consultant working for LACO

12 years of experience in SAS

9 years of experience in the Pharma
Industry in statistical programming

Experienced SAS trainer

Student at Open University
(Master of Science in Business
Process Management and IT)



Some 'fun' facts

Favorite sports: running,
cycling, skiing, ...

Favorite food: Italian,
Brazilian, Belgian , ...

Favorite music: roots music
(blues, jazz, country)



LACO



LACO has over 25 years experience in Business Intelligence, Performance Management and Application Development.

We have gained a lot of experience in specific business processes and company departments. Banking and insurance, pharmaceuticals, life sciences, healthcare and manufacturing are just some sectors in which we've built up specific expertise.

LACO N.V.

With more than 140 consultants, LACO is eager to help you to conduct your business even better.



Agenda

1. Global outsourcing and offshoring
2. Outsourcing and offshoring in the Pharmaceutical Industry
3. Acceptance of virtual work



Global outsourcing and offshoring



3 Broad Trends

1. Organizational relocation
- 2.
3. Geographical relocation
- 4.
5. The greater outsourcing and offshoring of activities that used to be considered 'Core'.

Offshoring and outsourcing start at home

1. The firm deconstructs itself (breaking down the value chain)
3. Devising appropriate interfaces between the organizationally and spatially separated functions
5. Minimizing transactions costs between the outsourced entities as well as minimizing global governance overheads



Driving factors



1. Reducing wages and costs
2. The drop in IT costs
3. Growing importance of foreign markets
4. Shortage of skilled technical and managerial personnel in the US and in Europe as the population ages
5. Acceleration in the rate of technical change
6. Greater codification of corporate knowledge
7. The modularization and distribution of tasks
8. ...

Starting point

Any business or technical operation that can be

- codified and
- digitized

is amenable to outsourcing and offshoring.

Many services can be stored and transmitted electronically.

In theory 11 percent (160 million jobs) of the 1.46 billion service jobs worldwide, could in theory be carried out remotely

Starting point



Constraining Factors



- The escalation of wages in the foreign location
- The persistence of tacit knowledge and embedded experience
- Transaction costs that can be avoided with vertical integration (negotiating, monitoring, coordination, quality control, etc.)

Constraining Factors



- Fears of supply chain disruptions
- Fear of misappropriation and leakage of knowledge to potential competitors
- Regulatory prohibitions and constraints on offshoring
- Certification and quality concerns

**Will high-value or
core functions
also be
outsourced and
offshored?**



Will high-value or core functions also be outsourced and offshored?



Companies today are even micro-dissecting and disaggregating their R&D into finer sub-segments which are distributed to different nations and external providers.

Will high-value or core functions also be outsourced and offshored?

R&D is no longer sacrosanct and monolithic piece of the value chain.

The globalization of research is still a minor, but accelerating, trend.

Will high-value or core functions also be outsourced and offshored?

A major reason is that multinationals need to tap into new knowledge and talented people anywhere on the globe.

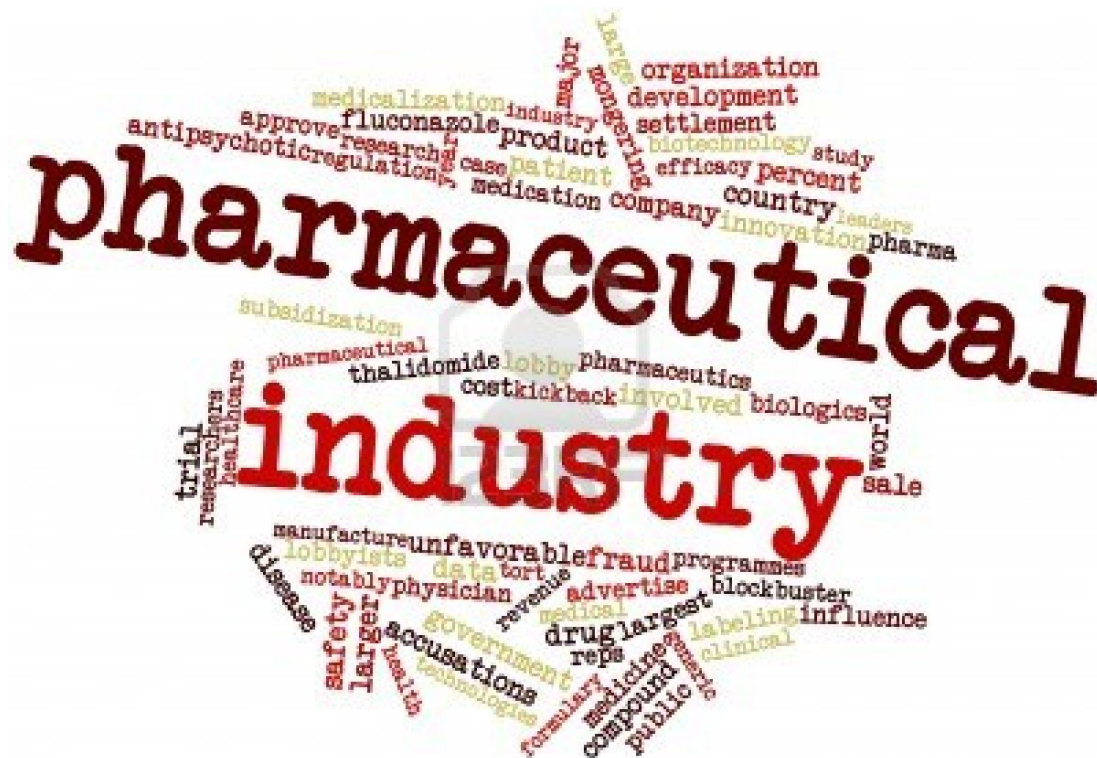
The search for foreign talent has risen to number two rank, just behind “cost savings” as a strategic driver for offshoring.

Will high-value or core functions also be outsourced and offshored?

The old adage, that a company must never outsource its core competencies, for fear of their loss to potential competitors, remains true.

However:

1. By offshoring R&D and innovation to affiliates, the multinational firma retains a considerable degree of secrecy and internal control
2. By artfully splitting the R&D function into vulnerable versus less vulnerable components, the latter can be outsourced to independent parties without much loss of competitiveness

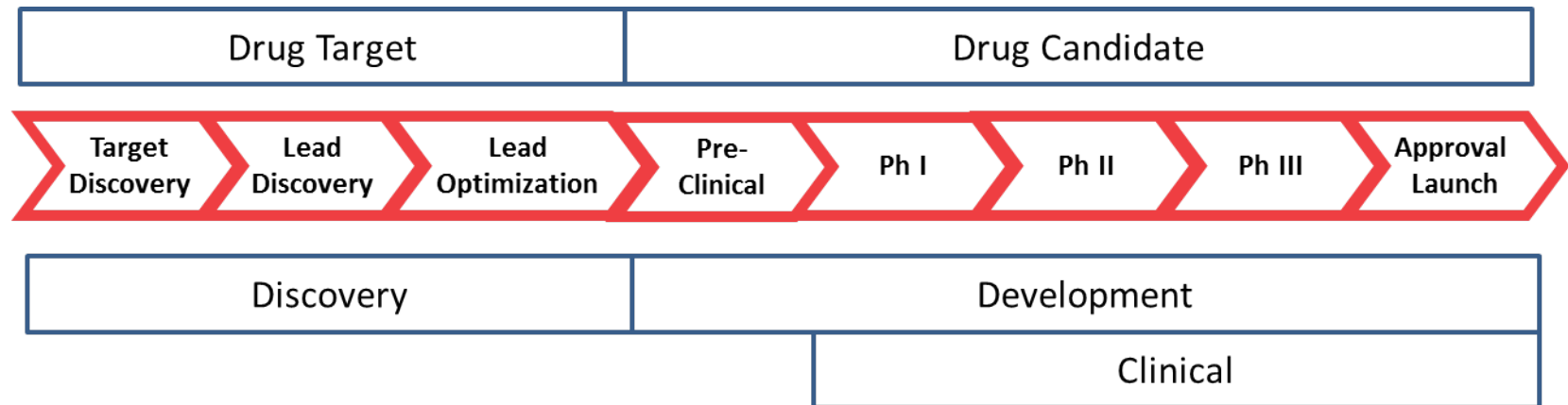


Offshoring and Outsourcing in the pharmaceutical industry

Drug Development

The management of drug development (clinical trials):

This function has been considered part of the core competences of pharmaceutical firms in the past, and both involve complex relationships rather than smooth interfaces between principal and vendor firms.



Drug Development

Until the late 1980s, pharmaceutical firms viewed outsourcing to be too risky given a lack of trust in the practices that might be adopted by outsider vendors.

Drug Development

But pressure to cap internal resources (fixed costs) and the rise of CROs led to limited outsourcing attempts, initially in response to strained internal capacity during peak activity.

Initially, some scientists/specialists relocating from pharma firms set up small, regional operations, specializing in clinical trial monitoring, project coordination, or data management.

Pressures (and opportunities)

The restructuring of the pharmaceutical industry has been explained (in the literature) within the context of:

- changing science and technology
- concerns about a dwindling drug discovery pipeline among the large pharma corporations
- the decline of the blockbuster drug model



Pressures (and opportunities)

- increasing price pressures from governments, world health authorities, and insurance entities,
- increasing competition in a globalized industry
- the fast-rising cost and length of development time to bring a new profitable drug to the market
- the declining proportion of new drug approvals
- losses to generic drugs and expiring patents.

Costs

The estimated cost of bringing a new drug to market had grown by a factor of almost six from 1979 to 1991.

For most of the past two decades, R&D costs have been rising at a faster rate than sales of ethical pharmaceuticals.



Costs

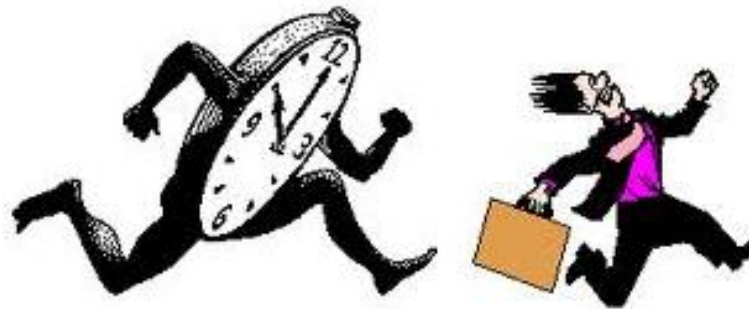
Data suggested higher costs and declining productivity.

According to the FDA, less than 8.1 percent of compounds discovered and placed in preclinical trials have reached the market in recent years, down from 14 percent in the 1990s.



Length

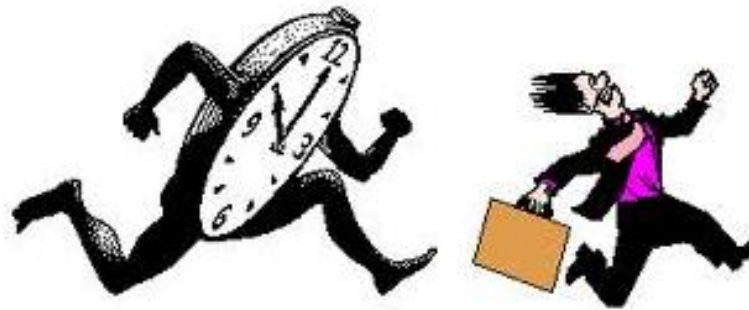
The length of time to bring a new drug from discovery to market is estimated 6.5 to 18 years from the preclinical phase to the end of regulatory review.



Who will win this race against time?

Length

The time-to-market has been growing in part due to the increasing concerns about safety on the part of the regulatory authorities.



Who will win this race against time?

Costs and Length

Some of the cost and time-to-market problems could very well be the result of the ongoing vertical disintegration within the industry.

Parexel reports from a survey of the industry that study delays were caused most often by the Pharma-CRO contract budget, negotiation, and approval process.

Reorganization

The reorganization of the industry has included:

- mergers and acquisitions among pharma firms to acquire new-capabilities, tools, and products for development
- mergers between pharma and biotech firms that allow pharma to acquire new scientific capabilities and that give access to development infrastructure to small biotech firms



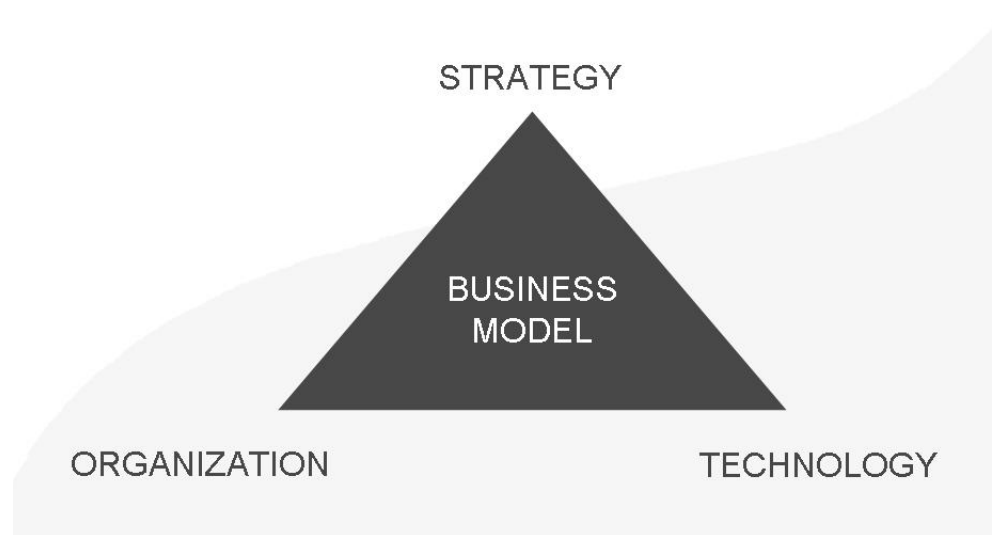
Reorganization

- mergers among contract research organizations to acquire a portfolio of capabilities
- vertical fragmentation of the discovery, development, and production process due to outsourcing and offshoring.



Reorganization

The variety of new forms is a manifestation of a trial-and-error search for a new business model to allow industry participants to compete successfully in a new environment.



Outsourcing and offshoring of drug development

Initial drug development outsourcing:

- ill-organized and
- labor-intensive



costly than expected.

Outsourcing and offshoring of drug development

In search for excellence!

The ideal of an outsourcing relationship characterized by an arm's length contract with a smooth interface, eliminating the need for costly coordination and monitoring expenditures has not been achieved.



Incomplete Control = Risk

Outsourcing= a solution to the peaks of demand for skilled clinical personnel without adding fixed costs in-house.

Problems:

- high labor turnover rate at CROs.
- CROs are unwilling to commit a dedicated team to a long-term trial

Incomplete Control = Risk



The pharma sponsors are continually "starting over" with new CRO staff with varying qualifications who unfamiliar with the product and trial history = continuity of procedures is not assured.

Incomplete Control = Risk



When contracts with CROs are focused on cost and speed, the incentives are not aligned to elicit learning, discovery, or creativity from CRO skilled personnel in response to problems that emerge, which adds to pharma's coordinating costs.

Incomplete Control = Risk



New risks due to pharma's incomplete control over CRO processes and personnel.



Incomplete Control = Risk



Extra layers of monitoring, i.e., much higher transaction costs than would normally be anticipated from an arm's-length arrangement.

Why engage in outsourcing of clinical trials?

There is some evidence that savings due to CRO specialization have been achieved.

Some reports show that CROs can shorten time to market significantly while preserving data quality; in some cases CROs can conduct clinical trials up to 30 percent faster than pharma firms.

Why engage in outsourcing of clinical trials?

They also bring experience from working in multiple therapeutic areas yielding skilled problem-solving abilities, and they have contacts and their own relationships with regulatory personnel.

Less costly interfaces

The industry is investing in the creation of interfaces that will facilitate less costly outsourcing in the future.

Standardization in drug development

Price, cost, productivity, and regulatory pressures have been felt across the industry.



Applied information technology presents the opportunity to speed up and automate parts of drug-development process.

Standardization in drug development



standardization

The FDA has been pushing the industry toward standardizing data collection and presentation, and announced in 2004 a preferred standard electronic format for submitting data in support of NDAs (New Drug Applications).

CDISC

The Study Data Tabulation Model (SDTM) format was developed by the Clinical Data Interchange Standards Consortium (CDISC), a global nonprofit multidisciplinary organization "committed to the development of industry standards to support the electronic acquisition, exchange, submission, and archiving of clinical trials data".

CDISC

CDISC has developed standards for each stage of the drug development process, including data transmission, data analysis, laboratory data, and non-clinical data, and standards cover both content of data files and processes such as data file formats, definitions and terminology, and submission procedures.

Goals

The goal is to create a single accepted format for data collection and exchange in order to create efficiencies in data collection and analysis of clinical trial data and in the review process by the FDA.

In addition, long-term goals include the ability to share information more readily among agencies, the ability to analyze data across trials for similar products, and to create a central repository for all clinical trial data.

Evolverment along two tracks

1.

The cost of monitoring a supposed arm's length relationship is to be replaced by collaboration with respect to best practices to increase the trustworthiness of future joint projects.

The CRO becomes a partner in innovation and problem solving.
(preferred suppliers – affiliates)



Evolverment along two tracks

2.

Both pharma and CROs are investing in new technologies and processes that are intended not only to reduce costs and speed innovation, but more specifically to standardize data and procedures and to codify and automate some skilled tasks.



Acceptance of virtual work in offshoring



Acceptance of virtual work in offshoring activities

3 research questions:

1. How does the introduction of distributed work change the work of professionals, such as the way individuals share their time between different projects and activities in different locations? (= *Integration with regular workflow*)
2. How do individuals in a globally distributed team interpret collaboration with offshore members? (= *Sense making of offshoring activities*)
3. How is collaboration influenced by professional identity and by the perception of offshore members' professional identity (= *Perception of differences in competences and professional identity*)?

Acceptance of virtual work in offshoring activities

Case studies were developed about two globally distributed teams of software engineers and developers belonging to Italian software companies offshoring their R&D to India and Tunisia.

Software engineers and developers perform knowledge-intensive, demanding, and individually styled work.

At the same time, to be successfully carried out, work needs a significant amount of interactions between team members.

Acceptance of virtual work in offshoring activities

We refer to the two companies that we studied as follows:

- (1) Dream, I with a globally distributed team composed of members located in Italy and India.
- (2) Core, with a globally distributed team composed of members located in Italy and Tunisia.

Acceptance of virtual work in offshoring activities

We looked for teams that were comparable in terms of governance form, nature of work, performance, stage of offshoring, and context characteristics.

Results

The results from our case studies of two globally distributed teams in organizations offshoring knowledge-intensive activities show that individuals have different work experiences and, accordingly, different levels of acceptance of virtual work.

Results

In particular, when

1. integration of conventional and virtual work practices is high
2. offshoring activities are interpreted as part of the regular workflow (and not as a disturbance)
3. professional identities and competences are perceived as different across locations, but team members share a common superordinate identity,

then GDT members accept virtual work.

Integration with regular workflow

Dream	Core
Processes and technologies were introduced with the aim of managing work at distance and integrating it with regular (local) work practice.  This resulted in a "uniform work practice" to be applied both to co-located and distant colleagues.	Interactions between sites happened in a special and dedicated environment (the conference room), and were not merged within everyday routine. The experience of multiple workspaces on one side (Italy), combined with the experience of a single workspace on the other (Tunisia), accentuates the perception of distance between individuals. Absence of formalized common processes.

Sense making of offshoring activities

Dream	Core
Communication by top management about offshoring rationale and performance. Overall effort of cultural integration. 	No communication by top management about offshoring rationale and performance. Small overall effort of cultural integration. 
High level of connectedness resulted in a smooth acceptance of virtual work.	Lack of organizational connectedness led to the perception of any activities related to offshoring as a disturbance to regular work practice.

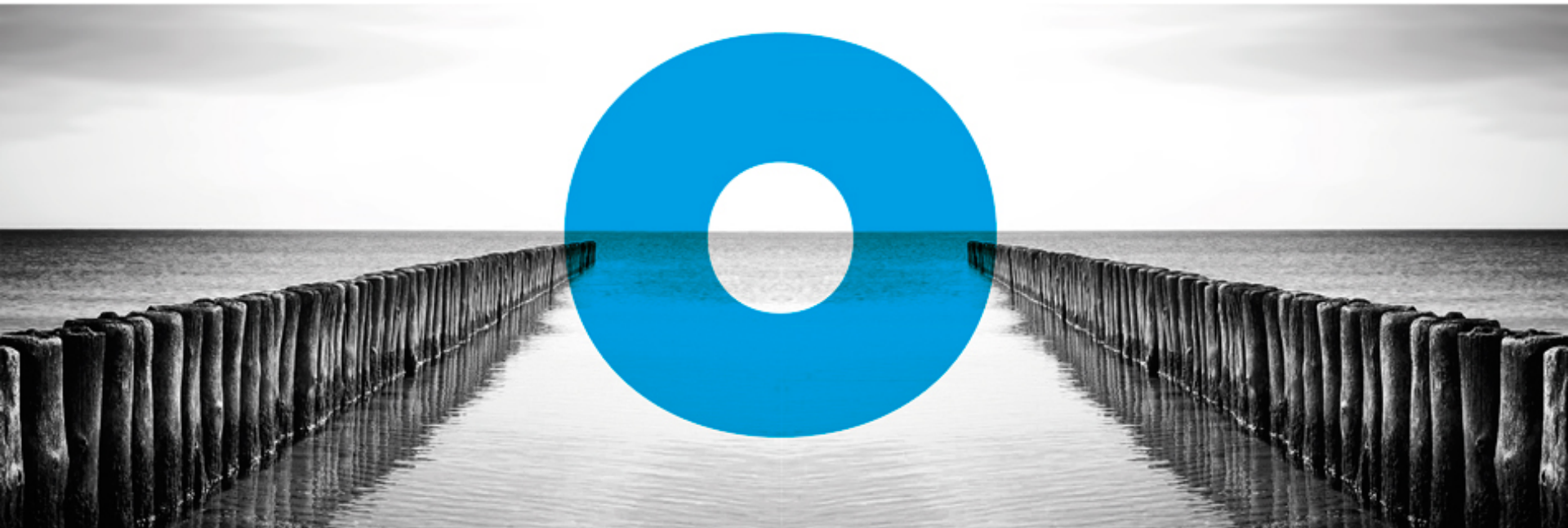
Perception of differences in competences and professional identity

In each of our cases, though, the functional and professional background of the members at the two locations is similar; what actually differs is the perception of themselves as professionals (i.e., their professional identity) and the perception of difference between one's own and other team members' professional values and beliefs.



Perception of differences in competences and professional identity

Dream	Core
Task conflict typically gets solved, because individuals are aware of the overall organizational mission, and are ready to move a step back for the organization's sake. The shared identity enacted is the very organizational identity, that is, the core, distinctive, and enduring values characterizing their employing organization.	Perceptions of competences of distant colleagues: Onsite: Analysts vs. Developers Offshore: Masters and students What is a common goal?



Q&A